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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,537	02/23/2004	Wadih Arap	UTSC:872US	2636
<div>7590 09/14/2007</div> <div>David L. Parker Fulbright & Jaworski L.L.P. Suite 2400 600 Congress Ave. Austin, TX 78701</div>				
EXAMINER				
LI, BAO Q				
ART UNIT		PAPER NUMBER		
1648				
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09/14/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,537	Applicant(s) ARAP ET AL.	
	Examiner Bao Qun Li	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 21, & July 06, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 4, 7-19, 21, 48-55 and 64-74 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10-19, 48-55, 67, 74-76 and 2, 8-9 in part is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 4, 8-9, 21, 65-66, 68-69, 70-73 is/are rejected.
- 7) ☒ Claim(s) 64 is/are objected to.
- 8) ☒ Claim(s) 7, 48-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

This is a response to the amendments filed on 06/12/07 and July 06, 2007. Claims 2, 7-12, 21, 48 and 64-69 have been amended. Claims 1, 3, 5-6, 20, 22-47, 56-63 have been canceled. New claims 70-76 have been added. Claims 2, 4, 7-19, 21, 48-55, 65-76 are pending before the examiner.

Election/Restrictions

1. Newly submitted amended claims 7, 48-52, 74-76 and claims, 2, 4, 8-9 in part are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the amended claims 7, 48-52, 74-76 and 2, 8-9 in part change the invention from an isolated peptide and a method to identify the isolated peptide cited in the original selected claim 1 to a method for manufacturing a peptide, wherein the method has much more broader scope than the original elected group of invention, different state of art and different issue than the original selected group of invention.

2. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

4. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

5. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

6. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 7, 10-19, 48-55, 67, 74-76 and 2, 8-9 in part directed to a method have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

8. Applicants are also reminded that claims 7 and 48-55 would be rejected with a new matter issue under 35 USC 112 1st paragraph since the amendment of claims has introduced a new matter that lacks support from the application as it was originally filed. Applicants are suggested to remove the new matter in order to avoid the rejection.

Rejoining the non-elected species of peptide sequences

9. Upon reconsidering the pending claims, the isolated peptides comprising one of the sequence set forth in SEQ ID NOs: 2-3, 5-6 are rejoined with elected species of SEQ ID NO: 1.

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10. Claims 2 and 8-9 in part and claim 4, 21, 64-66, 68-69 and 70-73 in the scope of peptides comprising one of the peptide set forth with SEQ ID NO: 1, 2, 3, 5, or 6 is considered. Claims 7, 10-19, 48-55, 67, 74-76 and 2, 8-9 in part that read on a method have been withdrawn from consideration.

Objection/Rejection withdrawn:

11. The objection of claim 20 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been withdrawn since claim 20 has been canceled by Applicants' amendment.

12. The rejection of claim 20 under 35 U.S.C. 102(a) as being anticipated by Mentzel et al. (Kidney International. 1999, Vol. 55, pp. 1335-1347) has been withdrawn necessitated by Applicants' amendment.

13. The rejection of claims 2, 7-9, 20 under *35 USC § 112, 1st* paragraph have been withdrawn necessitated by Applicants' amendment.

New Ground Objection/Rejection:

Priority

14. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e), 120 or 121 as follows:

15. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) for the US provisional Application SN. 60,231,266, filed on 8, 2000 has been denied for the following reasons: 1). The provisional Application had been expired prior to the current application was filed; and 2). The provisional Application lacks the enablement disclosure and written description under *35 USC § 112* to support the pending claims.

16. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 120 for the PCT/US01/27692 filed on Sept. 07, 2001 US has been denied for the following reason: 1). The PCT/US01/27692 lacks the enablement disclosure and written description under *35 USC § 112* to support the pending claims.

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17. The newly submitted amendment of claim 7 and all of the dependent claims thereof lack of support for an enablement description of manufacturing a peptide as APA inhibitor in vivo under **35 USC § 112**. Therefore, the benefit of the earlier filing date of PCT/US 02/27836, filed on August 30, 2002 has been denied.

18. It has been noted on the record that the peptide comprising SEQ ID NO: 1, 2, 3, 4, 5 or 6 cited in claim 4 has not been described in **PCT/US01/27692 and** US provisional Application SN. 60,231,266.

Specification

19. The disclosure is objected to because of the following informalities:

20. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code in paragraph [0167] of page 54 . Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Sequence requirements

21. This application contains sequence disclosure in paragraphs [0178], [0183] and [0203] that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

22. In the instant case, the sequences disclosed in the paragraphs lack of sequence identification number (SEQ ID NO).

23. Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Claim Rejections - 35 USC § 112

24. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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25. Claims 2 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

26. Claims 2 and 8-9 are confusing because it is unclear whether the claims are directed to a product or a method. One single claim cannot be drawn to a product and a method as well. A clarification is required.

Claim Rejections - 35 USC § 102

27. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

28. Claims 2, 4, 8-9, 21, 65-66, 68-69 and 70-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchio et al. (Aminopeptidase A binding peptides regulate endothelial cell function and inhibit angiogenesis in Tumori, (July-August, 2000, Vol. 86, No. 4, Suppl. 1. pp. 13).

29. (It is noted that the peptide of SEQ ID NOS: 1-6 were not described in the provisional Application NO. 60,231,266, filed on Sept. 08, 2000 and PCT/US 01/27692 on Sept. 07, 2001. Therefore, the cited prior art constitutes 102 (b) art).

30. Marchio et al. present a method for selecting a peptide that specifically binds to Aminopeptidase A (APA) over-expressed in angiogenic vessels. By screening phage display library on APA-transfected cells, they identify a specific APA-binding motif for such inhibitory peptides, i.e. a soluble peptide should have a consensus sequence of CPRECESID, which can specifically bind and inhibit APA enzyme activity. The peptide was further tested in proliferation and migration activity for the endothelial cells challenged with VEGF-A. They also teach that the APA-binding specific peptides that offer novel strategies for targeting tumor vasculature (See entire document). The peptide's consensus sequence of CPRECESID is the consensus sequence commonly own by the claims peptide comprising the SEQ ID NO: 2, 3, 5 and 6. Therefore, claims are anticipated by the cited reference.

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Conclusion

Claim 64 is free of rejection; however, it is not in condition for allowance because it depends on the rejection claim 4.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li
Bao Qun Li

09/11/2007

BAOQUN LI, MD
PATENT EXAMINER